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April 27, 1999

The Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street S.W.  
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Fen-Gre stimulates healthy function of the sinuses and the bronchial tubes.\*
- (2) Fenugreek has been shown to promote regularity, to help maintain healthy blood sugar and cholesterol, and to have gastrointestinal soothing properties as well. The seeds are rich in dietary fiber, which may be the reason fenugreek can help maintain healthy blood sugar levels and function as an intestinal stimulant.\*

These statements are made for a dietary supplement containing the proprietary blend of Fenugreek (seed), okra, and rice bran extract. Other ingredients include gelatin, water, calcium stearate, and natural colors. The name of the product is Fen-Gre®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden  
Standard Process Inc.

97S-0162

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